



AMERICA'S ESSENTIAL HOSPITALS

September 27, 2019

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Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Ave. SW
Washington, DC 20201

Ref: CMS-1715-P: Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations

Dear Administrator Verma:

Thank you for the opportunity to submit comments on the above-captioned proposed rule. America's Essential Hospitals appreciates the Centers for Medicare & Medicaid Services' (CMS') work to encourage improved care delivery across the health care industry. We are concerned, however, about the effect of cuts to Medicare payments for off-campus provider-based departments (PBDs) under the Bipartisan Budget Act of 2015 (BBA). These cuts deter hospitals from expanding access in communities with the most need for health care services and run counter to CMS' goal of integrated, coordinated health care.

America's Essential Hospitals is the leading champion for hospitals and health systems dedicated to high-quality care for all, including the vulnerable. Filling a vital role in their communities, our more than 300 member hospitals provide a disproportionate share of the nation's uncompensated care (UC), and three-quarters of their patients are uninsured or covered by Medicare or Medicaid. Our members provide state-of-the-art, patient-centered care while operating on margins one-fifth

that of other hospitals—1.6 percent on average compared with 7.8 percent for all hospitals nationwide.¹

Essential hospitals' commitment to serving all people, regardless of income or insurance status, and their diverse patient mix pose unique challenges. A disproportionate number of their patients face sociodemographic challenges to accessing health care, including poverty, homelessness, language barriers, and low health literacy. Ten million people in essential hospital communities have limited access to healthy food, and nearly 24 million live below the poverty line.² Essential hospitals are uniquely situated to target these social determinants of health and are committed to serving these vulnerable patients. These circumstances, however, compound essential hospitals' challenges and strain their resources, requiring flexibility to ensure essential hospitals are not unfairly disadvantaged for serving the vulnerable and can continue to provide vital services in their communities.

America's Essential Hospitals continues to have concerns about the unintended consequences if quality measures in the Medicare Shared Savings Program (MSSP) do not adequately account for sociodemographic factors. We also believe CMS should further examine how proposed changes to the program's methodology might affect accountable care organization (ACO) participation, given the agency's overhaul of the MSSP through the Pathways to Success rule, which created new participation tracks in 2019.

We support CMS' work to identify measures and activities that appropriately assess performance, promote quality of care, and improve outcomes through the Merit-based Incentive Payment System (MIPS) and alternative payment models (APMs) under the Quality Payment Program (QPP). We urge CMS to rigorously monitor, evaluate, and modify the QPP to ensure success across providers and settings as the program continues. To ensure alignment across Medicare programs and allow all providers the flexibility needed to be efficient and successful under the QPP, CMS should consider our recommendations before finalizing calendar year (CY) 2020 updates to the program.

Improving care coordination and quality while staying true to a mission of helping those in need can be a delicate balance. This balance is threatened by payment cuts to hospitals, such as those in CMS' proposed payment policy for non-excepted PBDs. To ensure our members have sufficient resources to advance their missions and are not unfairly disadvantaged for providing comprehensive care to complex patients, we urge CMS to consider the following recommendations when finalizing the above-mentioned proposed rule.

¹ Clark D, Roberson B, Ramiah K. *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2017 Annual Member Characteristics Survey*. America's Essential Hospitals. April 2019. www.essentialdata.info. Accessed September 6, 2019.

² Ibid.

1. CMS should ensure that non-excepted PBDs are adequately reimbursed for the costs of care.

As mandated by Section 603 of the BBA, CMS on January 1, 2017, discontinued paying certain off-campus PBDs under the Outpatient Prospective Payment System (OPPS). The BBA instructed CMS to pay these non-excepted PBDs under a Part B “applicable payment system” other than the OPPS; CMS determined the Physician Fee Schedule (PFS) to be such a system. **America’s Essential Hospitals urges CMS to reimburse non-excepted PBDs at no lower than 75 percent of the OPPS payment rate.** Doing so would ensure hospital PBDs are adequately reimbursed for the cost of providing comprehensive, coordinated care to complex patient populations in underserved areas.

In the CY 2017 OPPS final rule, CMS established an interim payment rate under the PFS for non-excepted items and services provided at non-excepted off-campus PBDs that is equivalent to 50 percent of the OPPS payment rate. CMS arrived at the 50 percent figure by comparing the PFS technical component payment rate to the OPPS payment rate for the 25 highest-volume services in off-campus PBDs, excluding office visits. Subsequently, CMS reduced the payment rate to 40 percent in the CY 2018 OPPS final rule. CMS since has maintained the relativity adjuster at 40 percent of the OPPS payment rate. To public knowledge, CMS has not analyzed how reduced reimbursement would affect patient access to care in PBDs or the differences between the patients treated at PBDs and physician-owned offices. Reduced payments to off-campus PBDs already impede the ability of essential hospitals to provide care to vulnerable patients in their off-campus PBDs. **We therefore urge CMS to ensure hospitals are adequately reimbursed for complex services provided in their PBDs.**

In the aggregate, members of America’s Essential Hospitals operate on margins one-fifth that of other hospitals nationally. For safety-net hospitals operating on these narrow (often negative) margins, this payment rate reduction is unsustainable. Patients at essential hospitals have felt the effects of the proposed payment rate more profoundly, given our members’ wide networks of ambulatory care in otherwise underserved communities. Essential hospitals often are the only providers willing to take the financial risk of opening a clinic in a community with many clinically complex and low-income patients. Inadequate payment rates affect patient access by limiting incentives for essential hospitals to bring health care into these communities of need. CMS’ implementation of Section 603—especially the inadequate payment rate—already has caused essential hospitals to re-evaluate plans to expand their provider networks into underserved areas.

By now, CMS must recognize the role the BBA and its implementation have played in limiting health care access for the country’s most disadvantaged patients. Patients seeking care at essential hospitals’ off-campus PBDs typically are low-income and racial and ethnic minorities. A significantly higher proportion of patients treated at essential hospital PBDs are dually eligible for Medicare and Medicaid, which is a key indicator of patient complexity. Dual-eligible beneficiaries tend to have poorer health status and are more likely to be disabled and costlier to treat compared with

other Medicare beneficiaries.³ In fact, CMS uses a hospital's proportion of dual-eligible beneficiaries as a proxy for adjusting the hospital readmission measures to recognize differences in sociodemographic factors. Essential hospital clinics often fill a void by providing the only source of primary and specialty care to these patients in their communities. Because of their integrated health systems, essential hospitals can help drive down overall health care costs, including for the Medicare program, by efficiently providing coordinated care through ambulatory networks.

It is worth noting that PBDs must comply with provider-based regulations, which include requirements pertaining to billing, medical records, and staffing. For example, an outpatient department must be clinically and financially integrated with the main provider and have full access to services at the main hospital to qualify as a provider-based facility and receive Medicare reimbursement. The department also must integrate its medical records into the main provider's system. These and other requirements impose additional compliance costs on hospitals that freestanding physician offices do not bear.

CMS has acknowledged it cannot directly compare payment to hospital PBDs and freestanding clinics because payment under the OPSS accounts for the cost of packaging ancillary services to a greater extent than payment under the PFS. For many services paid under the OPSS, including comprehensive ambulatory payment classifications, CMS makes a single payment for the main service and related packaged services. Comparing payment under the OPSS and PFS without accounting for the higher level of packaging that occurs under the OPSS understates the costs of services in hospital PBDs.

The Medicare Payment Advisory Commission (MedPAC) in a June 2013 report discussed equalizing payment across settings. MedPAC noted that any adjustment in payment rates to hospital PBDs should account for the higher level of packaging in the hospital setting by paying the hospital department at a higher rate than the physician freestanding office.⁴ **To adjust for the higher level of packaging in the OPSS, as well as higher costs incurred by hospital PBDs compared with freestanding offices, CMS should revise its payment rate for non-excepted items and services to at least 75 percent of the OPSS payment rate.**

By paying non-excepted hospital PBDs at 40 percent of the OPSS rate, CMS is grossly undercompensating hospitals for the services they provide to complex patients. **We urge CMS to increase the payment rate for non-excepted PBDs to adequately account for the higher acuity of patients they treat compared with physician offices.** Payment rates also should reflect the requisite resources, staff, and capabilities necessary for PBDs to both comply with other CMS regulations and provide high-quality care to all patients. Essential hospital PBDs offer culturally and linguistically competent care tailored to the disadvantaged patients in their

³ Medicare Payment Advisory Commission. *Data Book: Health Care Spending and The Medicare Program*. June 2018. http://www.medpac.gov/docs/default-source/data-book/jun18_databookentirereport_sec.pdf. Accessed September 9, 2019.

⁴ Medicare Payment Advisory Commission. *Report to the Congress: Medicare and the Health Care Delivery System*. June 2013. http://www.medpac.gov/docs/default-source/reports/jun13_entirereport.pdf. Accessed September 9, 2019.

communities. Whether due to the clinical complexity of their patients or the additional resources needed to provide translators and wraparound services, essential hospitals incur higher costs in treating their patients than other facilities. By considering the recommendations above, CMS can lessen the negative effect of Section 603 on disadvantaged patients' access to care.

2. CMS should continue to refine the methodology and measure set used to establish ACO quality performance standards under the MSSP, so it contains measures that accurately represent quality of care and does not introduce uncertainty to the program and ACO participants.

America's Essential Hospitals supports programs that encourage quality improvement. However, CMS must ensure that quality improvement program measures are properly constructed and do not lead to unintended consequences and administrative burden on hospitals. This is especially important for essential hospitals, which already operate with limited resources.

- a. CMS should account for sociodemographic factors, including socioeconomic status, by risk adjusting the measures used to establish ACO quality performance.

America's Essential Hospitals supports the creation and implementation of measures that lead to quality improvement. However, before including measures in the MSSP, CMS must verify they would not lead to unintended consequences. More than half of the 23 quality measures in the MSSP are related to outcomes. As quality reporting programs focus more on outcomes and move away from process measures, CMS must ensure that measures chosen for these programs accurately reflect quality of care and account for factors beyond a hospital's control. The agency should ensure the measure set includes metrics that are valid and reliable, aligned with other existing measures, and risk adjusted for sociodemographic factors. **CMS should not include measures in ACO quality performance standards until they have been appropriately risk adjusted for sociodemographic factors, including socioeconomic status.**

In previous comments on hospital inpatient and outpatient quality reporting programs, we urged CMS to consider the sociodemographic factors—language and existing level of post-discharge support, for example—that might affect patients' outcomes and include such factors in the risk-adjustment methodology. We made these comments out of a preponderance of evidence that patients' sociodemographic status affects outcomes of care.⁵ Outcome measures, especially those focused on readmissions, do not accurately reflect care quality if they do not account for sociodemographic factors that can complicate outcomes. For example, patients who do not have a reliable support structure are more likely to be readmitted to a hospital or other institutional setting. Reducing preventable readmissions is of paramount concern to America's Essential Hospitals and its members. We believe

⁵ See, e.g., America's Essential Hospitals. Sociodemographic Factors Affect Health Outcomes. October 21, 2015. <http://essentialhospitals.org/institute/sociodemographic-factors-and-socioeconomic-status-ses-affect-health-outcomes/>. Accessed September 7, 2019.

that any program directed at reducing readmissions and improving beneficiaries' health through the episode of care must target preventable readmissions and include appropriate risk-adjustment methodology.

Essential hospitals support quality and accountability. What they want—and what their patients and communities deserve—is equal footing with other hospitals for quality evaluation. When calculating quality measures, Medicare programs should account for the socioeconomic and sociodemographic complexities of disadvantaged populations to ensure hospitals are assessed on the care they provide, rather than on the patients they serve. Differences in patients' backgrounds might affect complication rates and other outcome measures; ignoring these differences would skew quality scores against hospitals that provide essential care to the most complex patients, including those with sociodemographic challenges and the uninsured. Further, failing to appropriately risk adjust can mislead and confuse patients, payers, and policymakers by not accounting for the effect of community factors that contribute to worse outcomes.

CMS should develop analytic methods for integrating patient data with information about contextual factors that influence health outcomes at the community or population level. Identifying which social risk factors might drive outcomes and how to best measure and incorporate those factors into payment systems is a complex but necessary task to ensure better outcomes, healthier populations, and lower costs. We look forward to working with CMS to account for social risk factors and reduce health disparities across Medicare programs, including the MSSP.

b. CMS should maintain the current MSSP quality scoring methodology.

Changes made in the CY 2019 PFS final rule reduced the MSSP quality measure set from 31 to 23 measures. These 23 measures span four domains—patient/caregiver experience, care coordination/patient safety, preventative health, and at-risk population. The minimum attainment standard under the MSSP specifies that ACOs must meet or exceed the 30th percentile (for pay-for-performance measures) on at least one measure in each of the four established quality domains to be eligible to share in any ACO-generated savings. After a domain score has been calculated for each domain using the methodologies described above, the four domain scores are weighted equally to calculate one quality score. CMS seeks comment on whether the agency should replace the current quality scoring approach for MSSP ACOs with the quality scoring approach used in MIPS.

For the 2018 QPP performance period and subsequent performance periods, the quality performance category under the MIPS APM scoring standard for MIPS-eligible clinicians participating in an MSSP ACO is assessed based on measures collected through the CMS Web Interface and the Consumer Assessment for Healthcare Providers System (CAHPS) for ACO survey measures. CMS scores performance with a percentile distribution separated by decile categories. The 30th percentile minimum attainment standard for the MSSP is the equivalent of the fourth decile performance benchmark under the MIPS APM quality performance category scoring. CMS recognizes that moving to a MIPS quality scoring approach

would hold ACOs to a higher minimum attainment standard by requiring a quality performance score at or above the fourth decile across all MIPS quality performance category scores to be eligible to share in ACO-generated savings. **We oppose proposals that would raise the minimum attainment level for MSSP ACOs.**

If CMS were to adopt the MIPS quality performance category score as the MSSP quality score, the agency no longer would transition from pay-for reporting to pay-for-performance during an ACO's first agreement period. Currently, in the first year of an ACO's first agreement period, all measures are scored as pay for reporting, meaning ACOs must completely and accurately report all quality data used to calculate and assess their quality performance. In the second and third year of the first agreement period and all years of subsequent agreement periods, measures are scored as pay for performance. There is value and necessity in providing ACOs, their clinicians, and support staff at least one year of preparation before they are held accountable for performance on a measure. **We oppose the removal of the pay for reporting year, as it would harm ACOs new to the program.**

We support the agency's work to seek greater alignment in quality measurement across Medicare programs, including alignment of methodologies. However, there are instances when alignment is not appropriate. For example, ACOs currently utilize a very different cost evaluation approach from MIPS, which CMS acknowledges by not scoring ACOs on cost in MIPS. ACOs are responsible for total cost of care for the population; therefore, CMS must use a different approach in evaluating ACOs compared with individuals or groups reporting quality measures in MIPS that are not participating in a total cost of care model. We believe this is another instance where alignment is not appropriate.

Further, given the recent changes to the MSSP's structure through the Pathways to Success regulation, which emphasize the transition of ACOs to risk-bearing models and accelerate the timeline for this transition, it would be inappropriate to introduce more uncertainty by overhauling the quality performance assessment approach for the MSSP. In this rule, CMS also proposes major overhauls in future years to the MIPS structure and approach with the MIPS Value Pathways (MVP). It is unclear how the quality scoring methodology may change in future years under the MVP framework and how these changes ultimately would affect ACO quality scoring. **We urge CMS to maintain the current quality scoring methodology for ACOs and focus on refining ACO quality measures within the existing MSSP structure and methodology.**

3. CMS should continue to refine the measures included in the MIPS—risk adjusting when warranted—and streamline efforts to focus on the highest-priority measures.

The implementation of the QPP in CY 2017 consolidated three existing physician quality programs into the MIPS. CMS previously finalized a methodology for assessing the total performance of each MIPS-eligible clinician through a composite score based on four categories: quality, cost, clinical practice improvement activities, and promoting interoperability.

America's Essential Hospitals supports creating and using measures that lead to quality improvement. However, measures finalized for inclusion in the MIPS must be properly constructed and not lead to unintended consequences. For the 2020 performance period, CMS proposes changes in each of the four MIPS performance categories.

- a. CMS should incorporate social risk factors in the risk adjustment of quality measures in the MIPS when warranted.

CMS should ensure the measure set includes metrics that are valid and reliable, aligned with other existing measures, and risk adjusted for sociodemographic factors to represent accurately the quality of care hospitals provide. Disadvantaged populations experience a disproportionate share of many diseases and adverse health conditions. Essential hospitals meet the complex clinical and social needs of all patients that come through their doors. As such, our members treat a high proportion of patients with social risk factors that fall outside the hospital's control and that can affect health outcomes, including lack of transportation for follow-up care and limited access to nutritious food. As CMS implements and monitors the third year of the QPP, **we continue to urge the agency to incorporate risk adjustment for social risk factors, including socioeconomic status, in the quality measures chosen for the MIPS.**

When calculating quality measures, Medicare programs should account for the sociodemographic and socioeconomic complexities of vulnerable populations to ensure clinicians are assessed on their work, rather than on factors outside their control. Additionally, differences in patients' backgrounds might affect complication rates and other outcome measures. For example, patients who do not have a reliable support structure at discharge are more likely to be readmitted to a hospital or other institutional setting. By ignoring these factors, CMS will skew quality scores against hospitals and clinicians that provide care to the most complex patients, including those with sociodemographic challenges and the uninsured.

We urge CMS to examine recommendations found in the 2016 report from the Assistant Secretary for Planning and Evaluation (ASPE) and the series of reports from the National Academies of Sciences, Engineering, and Medicine (the Academies) on accounting for social risk factors in Medicare programs, which includes examples of available data that could be included in measure risk adjustment.^{6,7} We look forward to working with CMS to account for social risk factors and reduce health disparities across Medicare programs, including the QPP.

⁶ Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation. *Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs*. Washington, D.C.; December 2016.

<https://aspe.hhs.gov/system/files/pdf/253971/ASPESESRTCfull.pdf>. Accessed September 7, 2019.

⁷ National Academies of Sciences, Engineering, and Medicine. *Accounting for Social Risk Factors in Medicare Payment*. Washington, D.C.: The National Academies Press; January 2017.

<http://nationalacademies.org/hmd/Reports/2017/accounting-for-social-risk-factors-in-medicare-payment-5.aspx>. Accessed September 7, 2019.

- b. We urge CMS to delay implementation of the All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions measure beyond the 2021 MIPS performance year, to ensure the measure is properly vetted and does not disproportionately penalize essential hospitals.

CMS proposes adding one administrative claims measure—All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions—for the 2021 MIPS performance period. This measure assesses patients who have two or more of the following nine chronic conditions:

- (1) acute myocardial infarction;
- (2) Alzheimer's disease and related disorders or senile dementia;
- (3) atrial fibrillation;
- (4) chronic kidney disease;
- (5) chronic obstructive pulmonary disease or asthma;
- (6) depression;
- (7) diabetes;
- (8) heart failure; and
- (9) stroke or transient ischemic attack.

The measure promotes improved management of multiple chronic conditions and coordinated care by assessing the unplanned hospital admissions for this high-risk population.

Research shows that proactively assisting high-need patients to meet their social and medical needs can reduce costly emergency department visits and hospital stays.⁸ Essential hospitals disproportionately serve vulnerable populations that require special considerations for their care because of lower socioeconomic status and multiple chronic conditions. Additionally, these patients have unmet social needs, such as access to safe housing, transportation, or healthy food. The Missouri Hospital Association in 2018 reported that, compared to all Missouri hospital patients, individuals diagnosed with social complexity have significantly higher rates of hospital utilization and social, behavioral, and clinical risk factors. Among patients diagnosed with housing problems, the rate of super-utilization of the emergency department was 26 times the utilization rate of patients without social complexity.⁹

The proposed measure does not adequately account for factors outside the provider's control that complicate care and affect admission rates for patients with multiple chronic conditions. Further, the measure has not gone through the Measures Under Consideration and the Measure Applications Partnership (MAP) process that is typically applied for all MIPS quality measures. **We urge CMS to delay implementation of the all-cause unplanned admission measure to allow**

⁸ Thompson MP, Podila MS, Clay C, et al. Community Navigators Reduce Hospital Utilization in Super-Utilizers. *American Journal of Managed Care*. 2018;28(2):70-76. <https://www.ajmc.com/journals/issue/2018/2018-vol24-n2/community-navigators-reduce-hospital-utilization-in-superutilizers>. Accessed September 9, 2019.

⁹ Reidhead M. *Decoding Social Determinants of Health*. Policy Brief. Missouri Hospital Association. September 2018. https://www.mhanet.com/mhaimages/Policy_Briefs/PolicyBrief_SDOH.pdf. Accessed September 9, 2019.

for further refinement, including examination of social risk factors that influence performance and the opportunity to go through the review process for MIPS measures.

- 4. CMS should finalize policies that reduce burden on clinicians in the promoting interoperability (PI) category of the MIPS and provide flexibility as providers transition to more difficult PI category requirements.**

We urge CMS to finalize changes to the PI category in the MIPS that will reduce burden and enable providers to deliver high-quality, patient-centered care. Since CY 2017, CMS has required eligible clinicians to use certified electronic health record technology (CEHRT) to report on measures in the advancing care information performance category (subsequently, the PI category), which counts for 25 percent of the MIPS composite performance score. In the 2019 final rule, CMS required clinicians to use exclusively the 2015 version of CEHRT. For 2020, CMS proposes to continue using the 2015 version of CEHRT. Further, CMS proposes several changes to the category to promote stability and reduce burden for providers.

- a. CMS should finalize a 90-day reporting period for CY 2021.

CMS should finalize its proposal to keep the 2021 PI category reporting period at 90 days, which offers much-needed stability for clinicians and provides flexibility as they become familiar with more difficult measures. Following the implementation of the 2015 CEHRT in 2019 and 2020, it will be crucial to provide physicians with continuity in the PI category by maintaining a 90-day reporting period for 2021. Additionally, many PI category measures—such as those requiring the use of APIs and health information exchange—are difficult for clinicians, so clinicians will benefit from additional preparation time resulting from a shorter reporting period. Keeping a 90-day reporting period in place for 2021 will give clinician practices additional time to adjust to the new measures and make system changes necessitated by new measures and the new scoring methodology. Accordingly, CMS should finalize the 90-day reporting period for CY 2021.

- b. CMS should remove the two opioid-related measures until the agency ensures adequate standards and specifications.

CMS should remove the two opioid-related measures under the electronic prescribing objective because of the lack of uniformity across states in the adoption of these practices, as well as a lack of standards and certification criteria. Essential hospitals are on the front lines of treating patients most affected by the opioid crisis and have implemented innovative strategies to reduce opioid dependence. As leaders in population health, essential hospitals continue to develop programs that prevent opioid misuse among vulnerable populations. They partner with pharmacies, public health departments, law enforcement, emergency medical services, and other community providers to combat the crisis. As key stakeholders in combating the opioid epidemic, essential hospitals stand ready to implement practices that have proved effective in reducing opioid dependence. While the intent

of using EHRs to fight the opioid crisis is commendable, there are significant barriers to the use of information technology to report the two measures CMS includes in the PI category.

CMS currently includes two opioid-related measures in the PI category:

- Query of Prescription Drug Monitoring Program: For at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a prescription drug monitoring program (PDMP) for prescription drug history, except where prohibited and in accordance with applicable law; and
- Verify Opioid Treatment Agreement: For at least one unique patient for whom a Schedule II opioid was electronically prescribed by the MIPS eligible clinician using CEHRT during the performance period, if the total duration of the patient's Schedule II opioid prescriptions is at least 30 cumulative days within a 6-month look-back period, the MIPS eligible clinician seeks to identify the existence of a signed opioid treatment agreement and incorporates it into the patient's electronic health record using CEHRT.

These measures were voluntary in 2019; for 2020, the opioid treatment agreement is voluntary and the PDMP measure is required. CMS proposes to eliminate the opioid treatment agreement measure and make the PDMP measure voluntary beginning in 2020. CMS also proposes to change the PDMP measure to require a “yes” or “no” attestation instead of reporting a numerator and denominator. We welcome these changes as a necessary step in the right direction. However, we urge the agency to continue to work toward PDMP integration before making the measure mandatory.

The PDMP measure is not ready for inclusion in the MIPS because it lacks uniformity of adoption across states and providers. PDMPs are state-level databases that can increase provider awareness of at-risk patients and thus reduce prescription drug misuse, but they are unevenly used across the country due to varying state requirements governing PDMPs. Not all states require the use of PDMPs and one—Missouri—does not even have a PDMP. Additionally, platforms differ by state, creating a lack of uniformity in accessing PDMP data and difficulty in establishing standards for the use of EHRs to access such data. There are no standards or certification criteria for the use of PDMPs or their integration into EHRs—CMS should work with other agencies to rectify this lack of uniform governance before requiring the use of these databases in the PI category.

In addition to the lack of standards and certification criteria, the use of PDMPs can cause workflow disruptions when practitioners check a patient's opioid medication history. Our members have indicated to us that accessing PDMPs can be an arduous process that requires the provider to close the EHR and provide credentials to log on to a state PDMP website. In other words, a provider cannot always seamlessly access PDMP information within the EHR when electronically prescribing a medication.

Until CMS can confirm PDMP integration and workflow issues are resolved, it should remove or keep voluntary the PDMP measure.

5. CMS should delay increasing the weight of the cost category and ensure measures in this category, including new episode-based measures, are fully vetted before use in the QPP.

America's Essential Hospitals and its members understand that the assessment of cost is vital to ensure clinicians provide high-value care to Medicare beneficiaries. For the first year of the QPP, the cost performance category was weighted at zero percent of the final MIPS score to give clinicians an opportunity to transition into the QPP. Over time, as mandated by the Bipartisan Budget Act of 2018 (BBA of 2018), the weight has increased, most recently to 15 percent for the 2021 MIPS payment year. The BBA of 2018 requires that, for each of the second through fifth years for which the MIPS applies to payments, not less than 10 percent and not more than 30 percent of the MIPS final score shall be based on the cost performance category.¹⁰

CMS proposes to increase the cost category weighting again (to 20 percent) for the 2022 MIPS payment year. MIPS-eligible clinicians have limited experience being scored on cost measures for the MIPS. **We urge the agency to maintain the 15 percent weighting of the cost category for the 2022 MIPS payment year.** Cost measures are still being developed, and clinicians do not have the same level of familiarity or understanding of these measures that they do of the quality measures. By delaying an increase in the weight for this category, clinicians and CMS will have the opportunity to gain familiarity with measures and data generated, without these measures affecting to a greater extent a clinician's total MIPS score.

The cost category includes a total per capita cost measure and a Medicare spending per beneficiary (MSPB) measure, as well as eight episode-based cost measures previously finalized for use in the 2019 performance period and beyond. CMS proposes to adopt 10 newly developed episode-based measures beginning in the 2020 performance year. Episode-based measures are designed to let attributed clinicians know the cost of the care clinically related to their initial treatment of a patient and provided during the episode's timeframe.

CMS only recently completed field testing in 2018 of the proposed episode-based measures and has not yet submitted the measures to the National Quality Forum (NQF) for endorsement. It would be premature to adopt these measures before understanding whether there might be unintended consequences or a need to adjust for social risk factors. For example, cost measures could disadvantage and/or discourage clinicians from providing care to the sickest and most complex patients. These patients with high care needs then could lose or face more limited access to care. To ensure measures are accurate and actionable, CMS should continue to evaluate attribution and risk adjustment models for these cost measures, including the potential adjustment for social risk factors. **We urge CMS to use the initial years of the QPP to provide feedback on new episode-based measures for**

¹⁰ Section 51003(a)(1)(C). Bipartisan Budget Act of 2018. Pub. L. 115-123, February 9, 2018.

informational purposes only and to obtain NQF endorsement before including these measures in the cost category for payment purposes.

Additionally, CMS proposes revisions to the total per capita cost measure and the MSPB measure, currently used in the MIPS. Revisions to the total per capita cost measure include changes to the attribution methodology to identify more accurately a beneficiary's primary care relationships, as well as the addition of service category and specialty exclusions. Events are excluded if performed by clinicians who frequently provide non-primary care services (e.g., radiation therapy) or are in specialties unlikely to be responsible for providing primary care (e.g., dermatology). The revised total per capita cost measure underwent MAP review and received a final recommendation of "do not support for rulemaking with potential for mitigation."¹¹

Likewise, the MAP urged CMS to continue testing the changes to the revised MSPB measure, which include removing costs that are unlikely to be related to the clinician and applying a new attribution model that distinguishes medical from surgical episodes. The MAP urged CMS to ensure that the revised MSPB measure produces the intended results and demonstrates validity and reliability at the National Provider Identifier level.¹² It is important that cost measures truly address factors within a clinician's reasonable control. **We urge CMS to conduct further testing of the revised total per capita cost and MSPB measures and obtain NQF endorsement before adopting either measure in the MIPS.**

We also have concerns about the potential for double counting clinician costs in the total cost measures and the episode-based cost measures. It is duplicative to assess performance in the MIPS cost performance category on both the per capita cost measures and episode condition measures. **We urge CMS to monitor for unintended consequences of the total per capita cost and MSPB measures to patients, such as undertreatment and reduced access to treatment for high-risk, high-resource use patients.**

6. We support CMS' proposal to maintain its policy of bonus points for MIPS-eligible clinicians who care for complex patients. We urge the agency to set a higher cap for such points and to consider social risk factors—in addition to the Hierarchical Condition Category (HCC) and dual-eligible status—when determining patient complexity.

For the 2020 and 2021 MIPS payment years, CMS finalized a policy that provides consideration for MIPS-eligible clinicians who care for complex patients by adding a complex patient bonus of up to five points to the final score. CMS intends to use this bonus structure as a short-term strategy to mitigate the potential effect of patient complexity on final scores. **We support CMS' proposal to maintain the complex**

¹¹ Measure Applications Partnership: *MAP 2019 Considerations for Implementing Measures in Federal Programs: Merit-Based Incentive Payment System (MIPS) and Medicare Shared Savings Program (SSP)*. Final Report. March 15, 2019. http://www.qualityforum.org/Projects/im/MAP/Clinician_Workgroup/2019_Considerations_for_Implementing_Measures_Draft_Report.aspx Accessed September 20, 2019.

¹² Ibid.

patient bonus points for the 2022 MIPS payment year. However, the need for such a bonus is continuous, and the effect of the bonus on the final score likely will be modest. We believe it is necessary to continue to provide such a bonus in future QPP years and potentially to increase the cap to more than five bonus points. **We urge CMS to extend its bonus strategy beyond the 2020 performance year.**

Further, CMS should do more to incorporate social risk factors into the MIPS scoring methodology. As the ASPE report to Congress indicated, providers filling a safety-net role have unmeasured differences in patient characteristics that might contribute to differences in outcome quality outside the hospital's control. Facilities, such as essential hospitals, and clinicians that care for patients with social risk factors face greater challenges than other hospitals, potentially disadvantaging MIPS-eligible clinicians who care for complex patients under the program.

For purposes of defining patient complexity, CMS examined two well-established indicators in the Medicare program: medical complexity as measured through HCC risk scores and social risk as measured through the proportion of patients dually eligible for Medicaid and Medicare. CMS acknowledged that these indicators are interrelated and, as such, paired the average HCC risk scores with the proportion of dual-eligible patients for the 2020 MIPS payment year. While we appreciate CMS' efforts to create a more complete complex patient indicator, this is but a first step. **CMS should consider and test additional variables when accounting for social risk factors to structure a bonus for treating complex patients.** We continue to urge the agency to closely examine the Academies' four recommended domains for risk indicators in federal programs:

- income, education, and dual eligibility;
- race, ethnicity, language, and nativity;
- marital/partnership status and living alone; and
- neighborhood deprivation, urbanicity, and housing.

Additionally, it is important that the methodology CMS uses is transparent so hospitals and stakeholders can replicate the agency's calculations. **We urge CMS to continue to engage stakeholders to develop a long-term complex patient bonus for the MIPS.**

- 7. CMS should engage stakeholders in the development of future frameworks for the QPP, including the MVP, to mitigate against any unintended consequences, appropriately encourage participation by essential hospitals, and account for differences in practice characteristics.**

CMS proposes to apply a new MVP framework to future proposals beginning in the 2021 MIPS performance period. The agency believes the new framework will reduce MIPS program complexity and the burden to participate. The MVP's "path to value" framework would connect measures and activities across the four MIPS performance categories—for example, by clinician specialty or health condition—and incorporate a set of administrative claims-based quality measures that focus on population health. Eventually, all MIPS-eligible clinicians would have to participate through an MVP or a MIPS APM.

We recognize CMS' desire to provide further options for eligible clinicians to participate in the QPP that might reduce their participation burden. However, in this era of evolving delivery and practice models, it is important to give clinicians, practices, and health systems the opportunity to assess the advantages and disadvantages of various reporting options under the MIPS. **We encourage CMS to seek further input from stakeholders as the agency looks to develop a new pathway for MIPS participation.**

CMS understands work is needed to develop a foundational population health quality measure set. Currently, the MIPS has one administrative claims-based quality measure: the all-cause readmission measure. To increase the use of global and population-based administrative claims-based quality measures, CMS proposes to add the all-cause unplanned admission measure for the 2021 MIPS performance year (as discussed above). The agency anticipates that this measure could be included in a population health quality measure set under the MVP framework. To ensure fair performance comparisons among clinicians, **we urge CMS to include appropriate risk adjustment for administrative claims-based quality measures.** Further, we encourage CMS only to include only measures in the MVP that are valid, reliable, and endorsed by organizations with measurement expertise, such as the NQF and its MAP. Through these NQF processes, measures are fully vetted and approved through a consensus-building approach that involves the public and interested stakeholders. **Measures should undergo review and obtain NQF endorsement prior to inclusion in the MVP.**

The most significant change with MVPs is that eventually, all MIPS-eligible clinicians would no longer be able to select quality measures or improvement activities from a single inventory. Instead, measures and activities in an MVP would be grouped by clinician specialty or condition. For example, an MVP for diabetes prevention and treatment could include quality measures on hemoglobin A1c control and high blood pressure evaluation, whereas an MVP for global surgery might include measure of surgical site infection and unplanned reoperation within a 30-day post-operative period. Cost measures for both MVPs could include the MSPB measure, but the major surgery MVP might also include a specific knee arthroplasty cost measure, for example.

Under the MVP framework, CMS no longer would require the same number of measures or activities for all clinicians; rather, it would focus on measures that best assess the quality and value of care within a specialty or condition. In other words, the exact number of measures and activities likely would vary across MVPs. As such, there could be instances in which certain specialties report on more measures simply because of measure availability or, in the case of multispecialty practices, that CMS believes could have more than one relevant MVP. To the extent that certain MVPs have more measures, or certain practices are required to report on multiple MVPs, this could lead to increased reporting burden. Essential hospitals that provide high-acuity care in multiple specialties—such as cardiology, oncology, cardiac surgery, advanced heart failure and transplant cardiology, critical care, and geriatrics—would feel the potential effect of this proposal most profoundly. **We urge CMS to ensure parity in the development and assignment of MVPs.**

CMS seeks comment on whether improvement activities, one of the four MIPS performance categories, should focus on improving the quality and cost within an MVP or broaden to include any improvement activities that are relevant to the practice. As CMS develops its approach to the MVP, **we urge the agency to examine the unique role essential hospital clinicians play in reducing disparities as well as improvement activities that promote health equity.** The mission to integrate health equity into care delivery and develop initiatives that target social determinants of health is embedded in the fabric of essential hospitals. Our members reach beyond their walls to understand what promotes or hinders health in their community and to partner with local organizations to deliver community-integrated health care. **We urge CMS to enable clinicians and practices to leverage existing efforts to fulfill requirements in the improvement activities category of an MVP.**

The agency also should examine operational considerations before implementing the MVP. For example, clinicians should have advance notice of the relevant MVP(s) for which they could potentially be required to report. Clinicians also should be afforded a choice when selecting an MVP (i.e., ability for self-assignment or selection of alternative MVP if assigned by CMS), and selecting measures and activities within an MVP. **CMS should mitigate any challenges or unintended consequences clinicians may experience in transitioning from MIPS to the MVP.**

Through the MVP framework development, CMS ultimately hopes to reduce barriers to clinicians' movement into APMs. America's Essential Hospitals supports CMS' efforts to develop the use of APMs and delivery models that strive to achieve the Triple Aim of better care, lower costs, and improved health. Shifting providers to APMs is one of the goals of the Medicare Access and CHIP Reauthorization Act, as reflected in the QPP, which offers bonus payments to eligible clinicians who participate in an Advanced APM and meet certain thresholds. However, providers differ in their readiness to adopt new delivery and payment models, such as the MIPS and APMs. Further, improving care coordination and quality while maintaining a mission to serve the vulnerable is a delicate balance. Essential hospitals often face challenges finding the resources necessary to upgrade technology, redesign processes, and develop a network; these challenges can preclude them from APM participation. Our members are not alone—many in the field struggle to transition effectively to APMs.

Additionally, as CMS noted, clinicians want timely performance feedback data on quality and cost to track their performance and determine the level of risk they might be able to take on in the future, as required in Advanced APMs. The agency has indicated willingness to consider performance feedback in their future work, such as the MVP framework. **We support efforts to provide enhanced feedback and data analysis information to clinicians; CMS should address this need irrespective of their development of a new MVP framework.**

Clinicians have only reported through the MIPS program since 2017. **We urge CMS to allow more time for clinicians to report through the program and more time**

for the agency to review participation results before implementing a variation on participation. Further, we believe there is work needed to improve and develop a foundational population health quality measure set that includes risk adjustment of measures when appropriate. This measure set cannot be completed by the proposed MVP start date in the 2021 performance year. **We encourage the agency to be thoughtful in its approach for any future QPP frameworks to not unduly burden providers serving complex patients.**

8. CMS should preserve access to complex care provided by specialists at essential hospitals through adequate reimbursement for evaluation and management (E/M) visits.

America's Essential Hospitals applauds CMS for its proposal to establish separate payment rates for the ten levels of E/M visits for new and established patients. In the CY 2019 rule, CMS finalized a policy to consolidate the payment rate for E/M visit levels 2 to 4 for new and established patients, which would have disproportionately affected providers serving the most complex patients. However, under CMS' current proposal, the agency will reverse its policy and pay separately for nine E/M codes and payment amounts for office visits: levels one through four for new patients (current procedural terminology [CPT] codes 99202–99205) and levels one through five for established patients (CPT codes 99211–99215).

Consolidating the payment rate for different visit levels, which indicate increasing resource intensity, would have undermined provider payment and patient access, particularly for vulnerable patients. CMS' finalized policy would have most profoundly affected specialties providing high-acuity care, such as cardiology, oncology, cardiac surgery, advanced heart failure and transplant cardiology, critical care, and geriatrics. These specialties involve time-consuming and resource-intensive visits that require a thorough evaluation of patients who might have multiple comorbidities. Such drastic payment reductions would have downstream effects on cancer patients, patients with complex heart conditions, and patients being treated for kidney failure. **We are encouraged that CMS considered stakeholder feedback and reverted to paying for E/M visits under 10 separate codes, which will account for the appropriate level of complexity for visits to providers offering high-acuity care.**

9. CMS should ensure the proposed bundled payments for overall treatment of opioid use disorder (OUD) account for the complexity of patients served by essential hospitals.

CMS proposes establishing bundled payments for the overall treatment of OUD, including management, care coordination, psychotherapy, and counseling activities. As proposed, the bundle would include two new Healthcare Common Procedure Coding System (HCPCS) G-codes to describe monthly service bundles that include the following office-based services for OUD treatment:

- overall management;
- care coordination;

- individual and group psychotherapy; and
- counseling.

CMS also proposes to include an add-on code that could be billed in circumstances when effective treatment for a patient requires additional resources that substantially exceed the resources included in the base codes.

America's Essential Hospitals supports increased access and care coordination in the treatment of OUD and other behavioral health conditions. Essential hospitals continue to be on the front lines of fighting the devastating opioid epidemic. As leading health care providers in their communities, essential hospitals see firsthand the harm caused by opioid misuse and seek to create innovative programs to educate their patients, treat patients already affected by an OUD, and offer long-term solutions. Essential hospitals are dedicated to prevention, both inside and outside their walls. These hospitals are leaders in implementing innovative programs that provide alternatives to opioids and working with their communities to increase awareness about the dangers of substance misuse. When substance misuse is already present, essential hospitals use evidence-based, integrated approaches to identify and treat OUD, including medication-assisted treatment, peer addiction counseling, and referral to community-based services. For example, an essential hospital in Massachusetts has been a national leader in addressing the opioid crisis, running the largest primary care office-based opioid treatment program in New England. The program employs a collaborative care model using nurse care managers to provide medication-assisted treatment to individuals with OUD.

- a. CMS should ensure reimbursement through the proposed bundle accounts for the complexity of patients essential hospitals treat for OUD.

Their disproportionately low-income, vulnerable patient populations put essential hospitals in a unique position to make a real and lasting impact on those living with OUD or in communities where the opioid epidemic is rampant. But treating this population presents challenges. Patients seeking this care at essential hospitals often face comorbid conditions or multiple addictions that make them more difficult to treat and require more costly care. It is crucial to consider OUD treatment in the context of a patient population that often faces social risk factors and barriers to care. **CMS should ensure the proposed bundle accounts for the complex patient populations essential hospitals treat for OUD and ensure reimbursement for these services adequately covers all associated costs.**

America's Essential Hospitals appreciates CMS' effort to account for increased complexity through the use of an add-on code for patients that require significantly more care than the types of care described by the base codes. If finalized, CMS should continue to monitor the utilization and effectiveness of this add-on code to account for increased complexity and adjust the add-on code as necessary to ensure adequate reimbursement for OUD services.

- b. CMS should provide adequate reimbursement for the complete array of services for patients with OUD, including alternative treatments for pain management.

The services included in CMS' proposed bundle for OUD treatment are limited to a set of office-based services that do not encompass the full spectrum of evidence-based care used to treat patients with OUD. **CMS should engage stakeholders about existing pain management programs and align incentives with compliance of evidence-based practices.**

Essential hospitals are national leaders in reducing opioid dependence through clinical practices that encourage the use of non-opioid alternative treatments. An essential hospital in New Jersey was the first hospital to develop an alternatives-to-opioids program in its emergency department that prioritizes the use of non-opioid treatments to manage acute pain. In the first two years of the program, the hospital decreased opioid prescriptions by 82 percent while continuing to meet patients' needs for pain relief for ailments such as renal colic pain, sciatica, headaches, musculoskeletal pain, and extremity fractures. These non-opioid treatments include other medications, ultrasound-guided nerve blocks, nitrous oxide, and trigger-point injections. While this essential hospital and others are developing pioneering approaches to combat the opioid crisis, prevailing cost and payment barriers hinder the use of non-opioid alternatives. **CMS should develop comprehensive payment mechanisms to encourage adoption of these alternative treatments.**

10. CMS should improve patient access to critical services by expanding Medicare coverage and payment for services provided through telehealth.

America's Essential Hospitals is encouraged that CMS seeks to add the proposed bundled services for OUD treatment to the list of services that are reimbursable as Medicare telehealth services. **We urge the agency to expand vulnerable populations' access to lifesaving services by broadening the scope of telehealth reimbursement and lifting barriers to Medicare reimbursement for these services.**

Technology can play a key role in linking patients to quality care. For example, telehealth expands the geographic reach of specialists and other providers, efficiently leveraging workforce capacities to connect patients to high-quality care, expand access, and improve population health. One essential hospital, in West Virginia, launched a telehealth program in 1993 and since has provided more than 20,000 telemedicine outpatient consultations, including for pediatrics, telestroke, and nephrology, to rural residents. Another essential hospital, in Utah, uses telehealth to manage complex patients with multiple chronic conditions through virtual visits and remote patient monitoring. In addition to providing dermatology, cardiology, prenatal care, and burn care through telehealth, this hospital provides state-of-the-art behavioral health services without requiring the patient to travel long distances for in-person care.

Coverage of telehealth services is limited to a list of specified services and subject to geographical limitations on the telehealth patient's location (the "originating site")

for the provider to receive Medicare reimbursement. In practice, lack of transportation and other barriers to access prohibit more than just rural patients from timely access to care. Even if these patients live in heavily populated urban areas, receiving a timely telehealth service from a physician can result in the early diagnosis of a life-threatening condition and play an important role in their follow-up care.

As discussed above, CMS proposes three new HCPCS G-Codes that describe bundling of services for OUD treatment. CMS also proposes to add these new HCPCS G-Codes to the list of services reimbursable as Medicare telehealth services because they are sufficiently similar to services currently on the telehealth list. **We urge CMS to finalize the addition of these codes to the list of services reimbursable as Medicare telehealth services and to continue to keep the list of telehealth services up-to-date and consistent with other payers, which tend to cover a wider variety of telehealth services than Medicare.**

Federal lawmakers and policymakers have realized the importance of telehealth in expanding access and seek ways to encourage providers to use telehealth. Congress eased some restrictions on telehealth reimbursement in the BBA of 2018, including lifting the requirement that a patient live in a rural area in specific contexts, such as for telestroke services and for ACOs. These changes represent an incremental step in the right direction and will enable some providers to reach more patients in need of care at a time and place that works for the patient. **To encourage a continued push toward coordinated care and improved care access, we urge CMS to explore additional policy changes using its regulatory authority, including through payment demonstrations.** For example, CMS could consider lifting the geographical limitation on telehealth services in the fee-for-service system.

In addition to their immediate implications for Medicare telehealth reimbursement and provider and patient access, policy changes will have downstream effects on other payers. As private payers and government agencies look to Medicare in determining what constitutes a patient-provider relationship, it is vital that Medicare not unreasonably restrict the scope of telehealth services.

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America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Senior Director of Policy Erin O'Malley at 202-585-0127 or eomalley@essentialhospitals.org.

Sincerely,

Bruce Siegel, MD, MPH
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